

Serial No. 10/642,363

Patent
13100-02CIP

REMARKS

Claims 1-25 are pending in the application.

Rejection Under 35 USC § 112, First Paragraph

Claims 7-20 have been rejected under 35 U.S.C. 112, first paragraph, because the specification allegedly does not provide enablement for the full scope of the claims. Applicants traverse this rejection. Reconsideration and withdrawal thereof are respectfully requested.

Applicants submit that the Examiner has failed to establish a *prima facie* case of non-enablement of the present invention. The Examiner has failed to set forth any reason why a person of ordinary skill in the art would not be able to practice the present invention given the disclosure in the present application.

When rejecting a claim under the enablement requirement of section 112, the Examiner bears the "initial burden of setting forth a reasonable explanation as to why [he/she] believes that the scope of protection provided by [the] claim is not adequately enabled by the description of the invention provided in the specification." *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). To object to a specification on the grounds that the disclosure is not enabling with respect to the scope of a claim sought to be patented, the Examiner must provide evidence or technical reasoning substantiating those doubts. *Id.*; and MPEP § 2164.04.

Without a reason to doubt the truth of the statements made in the patent application, the application must be considered enabling. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). The burden placed on the Examiner is reflected in the MPEP § 706.03.

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Accordingly, the case law makes clear that properly reasoned and supported statements explaining any failure to comply with Section 112 are a requirement to support a rejection. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

The Examiner has failed to establish why he/she believes that the presently claimed invention directed to the mannose YC-1 derivative for inhibiting expression of HIF-1 α in tumor cells is not enabled by the disclosure in the specification. In the absence of such evidence or scientific reasoning, Applicants submit that the present application must be considered enabling.

Applicants have demonstrated that the YC-1 compound has HIF-1 α inhibiting activity. Therefore, it is expected that the mannose YC-1 derivative would have HIF-1 α inhibitory activity as well. In the absence of evidence to the contrary, the specification must be considered to be enabling for the claimed invention.

Further, with respect to the Examiner's criticism of the specification for being enabling for inhibiting tumor growth of hepatoma cells in a xenograft, Applicants traverse this criticism.

Applicants note that while experimentation was done with hepatoma cells, it is not unrealistic to expand the usage of mannose YC-1 derivative to other tumor types, with a reasonable expectation that the growth of other tumor types would also be inhibited. Moreover, while it is true that the experimentation was conducted in a xenograft, Applicants should not be limited to the activity of mannose YC-1 derivative on xenografts only. Since the mouse that is used in the experimentation is a model in which tumor growth activity is typically monitored, it does serve as a model animal for testing the efficacy of anti-tumor agents. Therefore, the successful result in such xenografts as described in the present

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specification serves to provide an enabling disclosure for the claimed invention. Accordingly, withdrawal of this rejection is respectfully requested.

Rejection Under 35 USC § 112, Second Paragraph

Claims 19-20 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicants traverse this rejection. Reconsideration and withdrawal thereof are respectfully requested.

Applicants submit that claims 19 and 20 are definite. Since the mannose YC-1 derivative is effective for inhibiting a HIF-1 α activity, any disorder that is caused by HIF-1 α expression would be treatable with the mannose YC-1 compound of the presently claimed invention. Accordingly, the claim language is clear in this regard.

Conclusion

It is believed that the application is now in condition for allowance. Applicants request the Examiner to issue a notice of Allowance in due course. The Examiner is encouraged to contact the undersigned to further the prosecution of the present invention.

The Commissioner is authorized to charge JHK Law's Deposit Account No. 502486 for any fees required under 37 CFR § 1.16 and 1.17 and to credit any overpayment to said Deposit Account No. 502486.

Respectfully submitted,

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